

REMARKS

Claims 1 – 19 are pending in this application.

Claims 1 – 19 have been rejected.

Claims 1 and 10 are currently amended.

Amendments to the Claims

Claims 1 and 10 are currently amended to recite that the updated template is generated in response to the result on the comparing step or from the comparing means being an invalid template. This amendment is supported in claims 1 and 10 as originally filed and a page 23, lines 1 – 12 and throughout the specification. No new matter has been added.

Claim 1 has been further amended to recite that therapy is delivered to the heart based on the updated template. This amendment is supported at page 9, line 17 – page 10, line 2, page 11, lines 1 – 6 and page 11, line 19 – page 12, line 9, establishing that therapy is delivered based on the detection of tachyarrhythmia and that the methods described are utilized to detect ventricular tachycardia and fibrillation, as well as throughout the specification. No new matter has been added.

Rejections Under 35 U.S.C. § 112

Claims 1 – 19 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1 – 19 have been further rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. In particular, both sets of rejections derive from claim language in claims 1 and 10 which recited that the generation of the updated template occurred based on the result. It is noted that claims 1 and 10 have been recited to change the “based on the result” language to that the updating occurs “in response to the result being an invalid template.” Thus, it is respectfully submitted the amendments to claims 1 and 10 have

cured the basis for the rejections under both 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 112, second paragraph, and that the rejections of claims 1 and 10 should be withdrawn.

Claims 2 – 9 and 19 depend from claim 1 and claims 11 – 18 depend from claim 10, and as such incorporate all of the subject matter of the claims from which they depend. Because the grounds for rejection of claims 1 and 10 have been cured, it is respectfully submitted that the grounds for rejection of claims 2 – 9 and 11 – 19 under both 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 112, second paragraph, and that the rejections of claims 1 and 10 should be withdrawn.

Rejections Under 35 U.S.C. § 101

Claims 1 – 9 and 19 have been rejected under 35 USC § 101 because the claimed invention lacks patentable utility. In particular, claim 1 has been rejected for not being tied to a particular machine or apparatus, or not transforming an article into a different state or thing. It is noted that claim 1 has been amended to recite that therapy is delivered based on the updated template, thereby causing a therapy to be delivered, changing whatever delivers the therapy into a different state. Thus, it is respectfully submitted that the grounds for rejection of claim 1 under 35 USC § 101 have been cured and that the rejection of claim 1 should be withdrawn.

Claims 2 – 9 and 19 depend from claim 1 and as such incorporate all of the subject matter of claim 1. Because the grounds of rejection of claim 1 have been cured, it is respectfully submitted that the rejections of claims 2 – 9 and 19 under 35 USC § 101 have been cured and that the rejections should be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1 – 19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2002/0183637 (“Kim et al ‘637”) in view of U.S. Patent Publication No. 2002/0193695 (“Koyrakh et al ‘695”). These rejections are respectfully traversed.

Kim et al '637 discloses a normal cardiac rhythm template generation system and method. Cardiac signals are sensed, fiducial points are lined up, and a template is generated that is intended to be representative of a single cardiac beat (paragraph [0007]). Subsequently detected beats are utilized to confirm that the template is still representative of the patient's cardiac beats (paragraph [0008]). While data indicative of cardiac signals, such as RR intervals, are stored (paragraphs [0049] and [0071]), Kim et al '637 specifically discloses in two locations that multiple beats are not stored because analysis is conducted on a beat-by-beat basis (paragraphs [0082] and [0104]).

Koyrakh et al '695 discloses an automated template generation algorithm for an implantable device. A template having been created, a "normal" beat is collected and compared against the template to compute a match (Figure 8, reference numerals 238 and 240, and paragraph [0069]). If the beat is an unmatched beat a counter is incremented and compared against a total number of normal beats (Figure 8, reference numeral 246, and paragraph [0069]). If the fraction of unmatched beats to total beats exceeds a certain level, and the average of the unmatched beats is less than a threshold, the template is discarded and the process of template generation is restarted at step 160 in Figure 3 (Figure 8, reference numerals 248 and 250, and paragraphs [0040], [0069] and [0070]). As such, Koyrakh et al '695 does not show, disclose or suggest collecting a predetermined number of non-paced heartbeats during a second discrete sample collection interval, comparing the collected second events with a current template and generating an updated template from the second collected events. Rather, Koyrakh et al '695 specifically discloses that in the event that a particular number of non-paced, non-conforming beats are detected that the template is discarded and the template generation process is restarted without use of the beats which caused the original template to be discarded. As such, analysis is conducted on a beat-by-beat basis, and new template generation has nothing to do with the beats which are utilized in the analysis.

By contrast, claims 1 and 10, as amended, recite collecting the second selected events and then comparing the second selected events with the current template (e.g., claim 1, lines 9 – 17). If the current template is invalid an updated template is generated

from the collected second selected events (e.g., claim 1, lines 18 – 19). As noted above, Kim et al ‘637 specifically discloses that multiple beats are not stored and thus Kim et al ‘637 cannot show, disclose or suggest that the comparison with the current template occurs after the collection of the second selected events. Moreover, Kim et al ‘637 specifically recognizes the limitations of conducting a beat-by-beat analysis – if the analysis of the current beat is not finished, the subsequent beat may be skipped (paragraph [0075]). If enough beats are skipped then the template update is aborted until the next update time, but it is preferable that every beat is utilized. As such, while Kim et al ‘637 recognizes problems created by beat-by-beat analysis, Kim et al ‘637 does not recognize the solution to the problem offered by the subject matter of claims 1 and 10, as amended. Similarly, Koyrakh et al ‘695 simply conducts a beat-by-beat analysis of the template, and if the analysis indicates that the template is invalid the template is discarded and a new template is generated with new sensed beats. Thus, neither Kim et al ‘637 nor Koyrakh et al ‘695 show, disclose or suggest generating an updated template from the collected second selected events in response to the result being an invalid template, both merely disclosing a beat-by-beat analysis, and Koyrakh et al ‘695 disclosing subsequent template generation based on the analysis.

Neither Kim et al ‘637 nor Koyrakh et al ‘695 show, disclose or suggest all of the subject matter of claims 1 and 10, as amended, and instead teach away from the subject matter of claims 1 and 10 by specifically disclosing beat-by-beat analysis followed by subsequent regeneration of a template utilizing new beats. Thus, it is respectfully submitted that the rejections of claims 1 and 10, as amended, under 35 USC § 103(a) as being obvious over Kim et al ‘637 in view of Koyrakh et al ‘695 are improper and should be withdrawn.

Claims 2 – 9 and 19 depend from claim 1 and claims 11 – 18 depend from claim 10, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 2 – 9 and 11 – 19 recite additional patentable subject matter. Because the rejections of claims 1 and 10 are improper, and because of the additional patentable subject matter, it is respectfully submitted that the rejections of claims 2 – 9

and 11 – 19 under 35 USC § 103(a) as being obvious over Kim et al '637 in view of Koyrakh et al '695 are improper and should be withdrawn.

Summary

In view of the amendments made and the arguments presented, claims 1 – 19 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.


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Respectfully Submitted,

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